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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,774	01/24/2002	William R. Holmberg	1416.35US01	4594

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EXAMINER

SWEET, THOMAS

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 01/05/2004

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/056,774

Applicant(s)

HOLMBERG ET AL.

Examiner

Thomas J Sweet

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/24/03.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30-38 and 50 is/are allowed.
- 6) ☒ Claim(s) 1-6, 9-11, 13, 15, 16, 18, 19, 21, 23, 26, 39, 42, 44 and 48 is/are rejected.
- 7) ☒ Claim(s) 7, 8, 12, 17, 20, 22, 24, 25, 27-29, 40, 41, 43, 45-47 and 49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9-11, 13, 15-16, 18-19, 21, 23, 26 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Duran (US 5545215). Duran discloses a prosthesis (fig 9) comprising a reinforcement element (20) and a prosthetic conduit (28) of biocompatible material having a cylindrical section effectively ending in an expanded section with the reinforcement element at least a portion of which is positioned circumferentially at the junction there between.

With regard to claims 2-4, see column 3, lines 30-33 and 51 and column 6, lines 39-42.

With regard to claims 5-6, see column 3, lines 41 and column 7, lines 27-30.

With regard to claim 9, see figure 5b.

With regard to claims 10-11, the expanded section of figure 9 is about 10% larger than the average diameter and the expanded section of figure 11 is about 20% larger than the average diameter.

With regard to claim 13 and 15, see figure 11 valve leaflets 42.

With regard to claim 16, column 6, lines 39-48 states that a biocompatible synthetic membrane can be used in the making of the prosthesis including the valve. A polymer is mentioned as an example.

With regard to claim 18, see figure 7.

Art Unit: 3738

With regard to claim 19, part of reinforcing element 20 forms a ring.

With regard to claims 21 and 23, column 5 lines 1-6 state that metal or polymer can be used for element 20.

With regard to claims 26, see figure 9.

With regard to claim 39, a portion of the reinforcement element 20 is attached downstream from the valve.

Claims 42 and 44 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Klostermeyer et al (US 5891195). See figure 3.

Claim 48 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Fogarty et al (US 5824037). See figure 3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duran in view of Lapeyre et al (US 6068657). Duran discloses a prosthesis as discussed above. However, Duran does not disclose using a prosthetic valve which uses a rigid leaflet connected to an orifice ring. Lapeyre et al discloses a prosthetic valve which uses a rigid leaflet connected to an orifice ring

Art Unit: 3738

(fig 1a) designed to be mounted in the aortic position in the vicinity of the aortic sinus (col 7, line 22). It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the prosthetic valve of Lapeyre et al for the valve in the prosthesis of Duran since this amounts to mere substitution of one functionally equivalent prosthetic valve for another in the art of prosthetic aortic valves.

Response to Arguments

Applicant's arguments, see page 13-17, filed 11/24/03, with respect to claims 7-8, 12, 17, 20, 27-38, 40-41, 43, 45-47 and 49-50 and the Thurbrikar reference have been fully considered and are persuasive. The rejections of claims 7-8, 12, 17, 20, 27-38, 40-41, 43, 45-47 and 49-50 under 35 USC § 102(e) and 35 USC § 103(a) have been withdrawn.

Applicant's arguments with respect to claims 1-6, 9-11, 13, 15-16, 18-19, 21, 23, 26, 39, 42, 44 and 48 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

Claims 30-38 and 50 are allowed.

Claims 7-8, 12, 17, 20, 22, 24-25, 27-29, 40-41, 43, 45-47 and 49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Art Unit: 3738

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J Sweet whose telephone number is (703) 308-4018. The examiner can normally be reached on 6:30 am - 5:00pm, M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M McDermott can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

tjs


David H. Willse
Primary Examiner

Application/Control Number: 10/056,774

Page 6

Art Unit: 3738